

510(k) Summary

JUL 11 2006

510(k) Number: K061772

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR§807.92.

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Trade Name: TriActiv FX® Embolic Protection System

Common Name: Distal Occlusion Balloon Catheter

Classification Name: Device, Coronary Saphenous Vein Bypass Graft,
Temporary For Embolization Protection
(per 21 CFR Section 870.1250)

Regulatory Class: Class II

Device Product Code: NFA

Predicate Device: Kensey Nash Corporation's TriActiv® System
(K042040)

Date Prepared: June 22, 2006

Description of Device

The TriActiv FX® Embolic Protection System is a temporary balloon occlusion embolic protection device used during percutaneous coronary intervention of diseased saphenous vein grafts ranging from 3.0mm to 5.0mm in diameter. The device is comprised of four principal components: ShieldWire™ Balloon Guidewire ("balloon guidewire"), ShieldWire™ Inflator ("inflator"), FX™ Catheter ("flush catheter"), and AutoStream™ Flow Control ("flow control"). There are also four subcomponents or accessories included in the TriActiv FX® Embolic Protection System: the Split Tube Introducer, Shieldwire™ Guidewire Plug and Installer, TriActiv® Flow Control Power Supply and TriActiv® Tuohy. All TriActiv FX® Embolic Protection System components are supplied sterile and for single use only with exception of the TriActiv® Flow Control Power Supply which is non-sterile and reusable.

The balloon guidewire is advanced through the hospital-supplied 7F guide catheter (without sideholes) prior to percutaneous coronary intervention of a saphenous vein graft (SVG) and positioned just past the target lesion. The balloon is inflated with a medical grade carbon dioxide gas blend, creating a protected space between the guide catheter and the balloon. Once the balloon is inflated and vessel occlusion is confirmed, PTCA and/or stenting can be performed over the balloon guidewire. Immediately after intervention, the flush catheter is loaded on the end of the balloon guidewire and advanced into the graft. With the flush catheter positioned just proximal to the balloon, the flow control delivers saline through the flush catheter to gently wash the vessel and remove any debris generated during the intervention through the guide catheter into a collection bag. The TriActiv FX® Embolic Protection System has been designed to extract at a greater rate than it infuses to prevent aortic embolization. Once the physician is satisfied with the amount of debris removed from the vessel, the protection balloon is deflated and the device is removed.

1. *ShieldWire™ Balloon Guidewire*

The ShieldWire™ Balloon Guidewire is a single-use 0.014" stainless steel hypo-tube guidewire containing a latex distal protection balloon, which is used to occlude a 3.0mm to 5.0mm vessel. It is available in both standard (190cm) and exchange (300cm) lengths. The latex balloon is mounted over two inflation holes, which allow the balloon to be inflated with gas through the lumen of the hypotube. The use of a gas as an inflation medium, allows for rapid inflation and deflation of the protection balloon. The balloon is inflated using the ShieldWire™ Inflator attached to the proximal end of the guidewire. The physician estimates the vessel size and sets the inflation volume accordingly to occlude vessels between 3.0mm and 5.0mm. The guidewire is coated to reduce surface friction and allow for easier delivery of interventional devices. A radiopaque tip stop is soldered to the distal segment just proximal to the balloon. The tip stop prevents the interventional catheter from contacting the balloon and provides visualization under fluoroscopy. The split tube introducer is an accessory used to protect the balloon and floppy tip during introduction through the TriActiv® Tuohy valve. The proximal end of the guidewire is sealed with a removable guidewire plug to prevent debris or fluid from entering the lumen during catheter exchanges. Just prior to balloon inflation, the guidewire plug is removed from the proximal end of the guidewire. An additional guidewire plug is provided within a guidewire plug installer.

2. *ShieldWire™ Inflator*

The ShieldWire™ Inflator is a modified "syringe" that is pre-filled with a sterile, medical grade CO₂ gas blend and used to inflate the balloon. It contains a normally closed valve to lock onto the guidewire, a plunger with volume control that allows for incremental increases in gas and a mechanism to seal the end of the guidewire, which allows for protected catheter exchanges. The ShieldWire™ Inflator is pre-filled with enough gas to occlude a 3.0mm to 5.0mm vessel.

3. AutoStream™ Flow Control

The AutoStream™ Flow Control is a single use AC powered fluid flow control system with integrated tubing. The flow control incorporates mechanical pumps for fluid infusion and extraction as well as the tubing used to connect the flow control to the FX™ Catheter (infusion) and the TriActiv® Tuohy (extraction). The sterile flow control is powered by a reusable non-sterile power supply that is kept out of the sterile field. The flow control user interface incorporates 3 buttons and a digital numeric readout. A simple electronic circuit with a pre-programmed microprocessor controls all the functions of the unit. The TriActiv® Flow Control Power Supply is a non-sterile, reusable power cord used to provide power from an electrical outlet to the flow control. The TriActiv® Tuohy is a multiple port Tuohy-Borst valve that is attached to the guide catheter by a rotating luer and allows interventional access. It also provides an angiographic interface and port for extraction of debris.

4. FX™ Catheter

The FX™ Catheter is a catheter used to infuse saline and gently wash debris in the target vessel. The FX™ Catheter is a dual lumen catheter with a “rapid exchange” section. The FX Catheter is loaded on to the ShieldWire™ Balloon Guidewire to flush the target vessel after intervention. The distal end of the catheter incorporates an atraumatic tip with a radiopaque band to aid in placement.

Indication and Intended Use of Device

The TriActiv FX® Embolic Protection System is indicated for use in conjunction with percutaneous coronary intervention (PCI), using a 7F guide catheter (without side holes), of diseased saphenous vein coronary bypass grafts ranging from 3.0mm to 5.0m in diameter. The TriActiv® FX™ Embolic Protection System is intended to protect the distal coronary vasculature by trapping and extracting thrombotic and atheromatous debris liberated during PCI. The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral, carotid, or peripheral vasculature; native coronary arteries; or for treatment of patients with acute myocardial infarction.

Technological Characteristics

The TriActiv FX® Embolic Protection System is the “next generation” of the TriActiv® System. The technological characteristics are substantially equivalent to the “previous generation” with the following differences:

- The balloon guidewire and inflation components (“ShieldWire™ Temporary Occlusion Balloon Guidewire” and “Balloon Inflation Syringe” respectively) of the TriActiv® System were modified to allow for multiple device exchanges over the balloon guidewire during balloon occlusion. The TriActiv FX® Embolic Protection System design incorporates a mechanism into the inflation component (“ShieldWire™ Inflator”) to seal the proximal end of the guidewire (“ShieldWire™ Balloon Guidewire”) upon user deployment.

- The TriActiv® System's flush catheter ("FlushCath™ Catheter") was redesigned from a "side-attachable" catheter to a "rapid exchange" type catheter ("FX™ Catheter") which physicians are more accustomed to using. The original "side-attachable" version also requires an Attachment Tool, which is no longer necessary since the FX™ Catheter simply is loaded onto the end of the balloon guidewire.

Non-Clinical and Clinical Summary

Non-clinical verification and validation of the TriActiv FX® Embolic Protection System has been performed through extensive in vitro bench testing, biocompatibility testing, software validation, electrical safety testing, package integrity testing, shelf life testing, and in vivo animal studies. Results of this testing indicate that the TriActiv FX® Embolic Protection System design meets all specifications and intended use.

Clinical evaluation of the TriActiv® FX™ Embolic Protection System was conducted in the prospective, multi-center, non-randomized ASPIRE (Angioplasty in SVGs with Post Intervention Removal of Embolic Debris) Study. The purpose of the ASPIRE Study was to establish the safety and performance of the TriActiv® FX™ System during percutaneous coronary intervention (PCI) of diseased saphenous vein grafts (SVGs). The data from the ASPIRE Study was compared to historical control data; patients in the Active Control group from the PRIDE Study. The Active Control group consisted of patients that were randomized to control and were to receive either the Guardwire® Plus System or the FilterWire® EX System. A total of 113 patients were enrolled in the study, at 17 U.S. and 3 German investigational sites, between March 2005 and November 2005. Investigators in the study were allowed up to 3 "roll-in" patients, for training purposes, which accounted for 20 of the 113 patients.

The primary endpoint analysis was adjusted based on subclassifications from a propensity score analysis. All baseline variables from patients in ASPIRE and in the Active Control group from PRIDE were combined and analyzed by a stepwise logistic regression with patient cohort as the outcome variable. These probabilities were then sorted and patients were grouped to form five patient strata of equal size. These resulting strata were then used as a stratification variable in all analyses that compared the two patient groups. The primary endpoint results were tested to determine non-inferiority.

The patient populations in the ASPIRE Trial and the Active Control Arm of the PRIDE Trial were generally similar. Patients in the Enrollment Phase of the ASPIRE Trial had an observed 30-day MACE rate of 3.2% (3/93). This was compared to the 30-day MACE rate observed in the Active Control Arm (the Medtronic Guardwire® or the Boston Scientific Filterwire EX™) of the PRIDE Trial, 10.1% (32/318) [Difference of -6.8% (upper 95% C.I. -2.7%)]. Following the propensity score analysis, these data demonstrated that the TriActiv® FX™ System is not inferior to the Active Control Arm from PRIDE ($p < 0.001$). Patients in ASPIRE also had a lower rate of all myocardial infarctions than patients in the Active Control group from the PRIDE Study [2.2% vs. 8.8% respectively, (Difference of -6.7% (upper 95% C.I. -3.1%))].

Table 1: ASPIRE Principle Results

| | ASPIRE Enrollment Phase (N=93) n (%) | PRIDE Active Control (N=318) n (%) | Adjusted P-Value | Unadjusted Difference (95% CB) ² |
|--|--------------------------------------|------------------------------------|------------------|---|
| MACE to 30 days | 3 (3.2%) | 32 (10.1%) | 0.013 | -6.8% (-2.7%) |
| Death | 0 (0%) | 2 (0.6%) | - | -0.6% (0.1%) |
| Cardiac | 0 (0%) | 2 (0.6%) | - | -0.6% (0.1%) |
| Non Cardiac ³ | 0 (0%) | 0 (0%) | - | - |
| MI | 2 (2.2%) | 28 (8.8%) | 0.021 | -6.7% (-3.1%) |
| Q wave | 0 (0%) | 1 (0.3%) | - | -0.3% (0.2%) |
| Non-Q wave | 2 (2.2%) | 27 (8.5%) | 0.022 | -6.3% (-2.8%) |
| TVR | 1 (1.1%) | 4 (1.3%) | 0.41 | -0.2% (1.9%) |
| MACE-in-hospital | 2 (2.2%) | 29 (9.1%) | 0.015 | -7.0% (-3.3%) |
| Stroke-in-hospital | 1 (1.1%) | 1 (0.3%) | 0.70 | 0.8% (2.6%) |
| Stroke to 30 days | 1 (1.1%) | 1 (0.3%) | 0.70 | 0.8% (2.6%) |
| Hemorrhagic/vascular complications to 30 days | 2 (2.2%) | 21 (6.6%) | 0.21 | -4.5% (-1.8%) |
| Transfusion to 30 days | 0 (0%) | 13 (4.1%) | - | -4.1% (-2.3%) |
| Device Success⁴ | 89 (95.7%) | 293/310 (94.5%) | 0.79 | 1.2% (-2.9%) |
| Procedure Success/Patient⁵ | 90/92 ⁷ (97.8%) | 286/316 (90.5%) | 0.013 | 7.3% (3.6%) |
| Lesion Success/Lesion⁶ | 103/103 ⁷ (100%) | 319/321 (99.4%) | - | 0.6% (-0.1%) |
| Final TIMI Flow | | | | |
| 0 | 0 (0%) | 2 (0.6%) | | |
| 1 | 0 (0%) | 2 (0.6%) | | |
| 2 | 4 (4.1%) | 3 (0.9%) | | |
| 3 | 93 (95.9%) | 313 (97.8%) | 0.98 | |

¹Two-sided p-value comparing ASPIRE Enrollment Phase and the PRIDE Active Control adjusted for propensity score groups

²Difference in percentages between ASPIRE Enrollment Phase and the PRIDE Active Control (one-sided 95% upper confidence bound on the difference)

³Non-cardiac death is not a MACE as defined in the protocol, but is shown for comparison to cardiac death, which is a MACE as defined in the protocol

⁴Device success is defined as attainment of all of the following: the device was successfully delivered to the target location, the device operated as intended, the device was successfully retrieved.

⁵Final stenosis < 50% by QCA for all lesions and no in-hospital MACE.

⁶Final stenosis < 50% by QCA

⁷Pt 14-003 censored. TriActiv FX System used for IVUS lesion evaluation. No PCI. Medical treatment only.

Statement of Substantial Equivalence:

Kensey Nash Corporation considers the TriActiv FX® Embolic Protection System substantially equivalent to the TriActiv® System (K042040) based on comparison of intended use and the results of in-vitro testing, in-vivo testing and clinical evaluation.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2006

Kensey Nash Corporation
c/o Ms. Robin Fatzinger, RAC
V.P. of Clinical & Regulatory Affairs
735 Pennsylvania Drive
Exton, Pennsylvania 19341

Re: K061772

Trade/Device Name: TriActiv FX Embolic Protection System
Regulation Number: 21 CFR 870.1250
Regulation Name: Distal Embolic Protection Guidewire
Regulatory Class: Class II
Product Code: NFA
Dated: June 22, 2006
Received: June 23, 2006

Dear Ms. Fatzinger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Robin Fatzinger

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Anna R. Vachner

BR Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 - Indications for Use Statement

510(k) Number (if known): K061772

Device Name: **TriActiv FX® Embolic Protection System**

Indications for Use:

The TriActiv FX® Embolic Protection System is indicated for use in conjunction with percutaneous coronary intervention (PCI), using a 7F guide catheter (without side holes), of diseased saphenous vein coronary bypass grafts ranging from 3.0mm to 5.0m in diameter. The TriActiv FX® Embolic Protection System is intended to protect the distal coronary vasculature by trapping and extracting thrombotic and atheromatous debris liberated during PCI.

The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral, carotid, or peripheral vasculature; native coronary arteries; or for treatment of patients with acute myocardial infarction.

Prescription Use **X**

(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use _____

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

James R. Wachter

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K061772